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Attorney Docket No.: DEX-0117
Inventors: Salceda et al.
Serial No.: 09/721,183
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be pending. However, only claims 1, 2 and 8-17 were canceled by Applicants in the last response. Thus, claims 6 and 7 are also still pending.

Claims 18-37 have been acknowledged as allowed by the Examiner.

Claims 3-5 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention. The Examiner suggests that the written description sets forth only SEQ ID NO: 1, 2, 3, 4, 18 or 20 and is therefore insufficient to support the genus of BCSG upon which the method claims depend. The Examiner suggests that the recitation of BCSG without a sequence identifier refers to a genus of polynucleotide encompassing full genes, allelic sequence, splice variants and mutant genes and mRNAs, as well as fragments of BCSG-1 through 5 which can hybridize to the antisense of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claims 3-7 to clarify that the BCSG polynucleotide comprises SEQ ID NO:1, 2, 3, 4, 5, 18 or

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20 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20. Applicants believe that these amendments, which are clearly supported by the specification at page 3 (lines 2-26), 4 (lines 4-11) and 7 (lines 3-34) and claim 1 as originally filed, set forth definitive structural features of the claimed polynucleotides so that one of skill in the art can predictably identify the encompassed molecules as being identical to those now claimed. Further, the claims as amended describe distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention. See MPEP § 2163.02. Thus, the claims as amended meet the written description requirements of 35 U.S.C. § 112, first paragraph.

Withdrawal of this rejection is therefore respectfully requested.

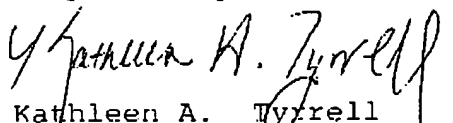
Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

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Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend the claims as follows:

3. (amended) A method for diagnosing the presence of breast cancer in a patient comprising:

(a) determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in cells, tissues or bodily fluids in a patient; and

(b) comparing the determined levels of BCSG polynucleotide with levels of BCSG polynucleotide in cells, tissues or bodily fluids from a normal human control, wherein an increase in determined levels of BCSG polynucleotide in said patient versus normal human control is associated with the presence of breast cancer and wherein the BCSG polynucleotide comprises SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20.

4. (amended) A method of diagnosing metastases of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

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(b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in cells, tissues, or bodily fluid from said patient; and

(c) comparing the determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissue, or bodily fluid of a normal human control, wherein an increase in determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20.

5. (amended) A method of staging breast cancer in a patient having breast cancer comprising:

(a) identifying a patient having breast cancer;
(b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in a sample of cells, tissue, or bodily fluid from said patient; and

(c) comparing determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in determined BCSG polynucleotide levels in said patient versus the

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normal human control is associated with breast cancer which is progressing and a decrease in the determined BCSG polynucleotide levels is associated with breast cancer which is regressing or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO:1, 2, 3, 4, 5, 18 or 20 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20.

6. (amended) A method of monitoring breast cancer in a patient for the onset of metastasis comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) periodically determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in samples of cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO:1, 2, 3, 4, 5, 18 or 20 or a polynucleotide which hybridizes under

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stringent conditions to the antisense sequence of SEQ ID NO: 1,
2, 3, 4, 5, 18 or 20.

7. (amended) A method of monitoring a change in stage of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer;

(b) periodically determining levels of Breast Cancer Specific Genes (BCSG) polynucleotide in cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which is progressing in stage and a decrease is associated with breast cancer which is regressing in stage or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO:1, 2, 3, 4, 5, 18 or 20 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20.